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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
	10/566,944	ZANK ET AL.		
Office Action Summary	Examiner	Art Unit		
	Elizabeth F. McElwain	1638		
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the o	correspondence address		
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION (36(a). In no event, however, may a reply be tirce will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) ☐ Responsive to communication(s) filed on 25 F 2a) ☐ This action is FINAL. 2b) ☐ This 3) ☐ Since this application is in condition for allowa closed in accordance with the practice under E	s action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 1-34 is/are pending in the application 4a) Of the above claim(s) 12-34 is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-11 is/are rejected. 7) ☐ Claim(s) 2-4 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	wn from consideration. or election requirement.			
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	cepted or b) objected to by the drawing(s) be held in abeyance. Settion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) 1) \[\sum \text{Notice of References Cited (PTO-892)} \]	4) ☐ Interview Summary	(PTO-413)		
 Notice of References Cited (PTO-052) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/8/10, 5/18/10. 	Paper No(s)/Mail D. 5) Notice of Informal F 6) Other:	ate		

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DETAILED ACTION

Election/Restrictions

1. This application contains claims 12-34 drawn to an invention nonelected with traverse in the reply filed on April 15, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

Claims 2-4 are objected to for reciting nonelected SEQ ID numbers. Amendment of the claims to delete the nonelected subject matter is requested. Alternatively, applicant could make a statement on the record that the sequences are obvious one over the others and therefore do not constitute different inventions.

- 2. Applicant's arguments filed February 25, 2010 have been fully considered but they are not persuasive. Applicants state that the sequences corresponding to non-elected enzymes having delta-8 and delta-9 activity have been deleted. However, applicants have not deleted the other non-elected sequences, as they interpreted the restriction of sequences as an election of species.
- 3. The Examiner maintains the objection given that the restriction requirement with regard to the sequences is not an election of species. As stated in the restriction requirement, the sequences are independent and distinct inventions and the "requirement is not be construed as a requirement for election of species". The objection is maintained, but will be reconsidered if allowable subject matter is identified for a generic claim.

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Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 3 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/590,958.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 of Application No. 10/590,958 is drawn to a method of making polyunsaturated fatty acids in an organism by transforming the organism with an omega-3 desaturase coding sequence in combination with other fatty acid biosynthesis genes., which would be obvious in view of the present claim drawn to a method of making polyunsaturated fatty acids in an organism by transforming the organism with an omega-3 desaturase coding sequence and optionally together with other fatty acid biosynthesis genes

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Applicants' arguments filed February 25, 2010 have been fully considered but they are not persuasive. Applicants respond that they will consider filing a terminal disclaimer upon an indication that the claims are allowable.

4. The Examiner will maintain the rejection until a terminal disclaimer is filed. Applicant is advised that a Notice of Allowability will not be issued until the terminal disclaimer is filed and approved.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1 and 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Drexler et al (J Plant Physiol 160 (7): 779-802, July 2003 in IDS and cited in the International Search Report).
- 7. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism

coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase.

- 8. Drexler et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in a plant by introducing into the plant coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase (see pages 794-796 and Figure 6, for example), wherein the biosynthetic pathway is known and genes for each of these enzymes are cloned from numerous eukaryotic organisms and bacteria. Drexler et al also teach transformation of canola (Brassica) with desaturase coding sequences (page 796, the last full paragraph) to produce polyunsaturated fatty acids (18:3). And the recited substituents of R2 and R3 and the percentage of Formula I compounds would be inherent in the same process.
- 9. Applicants' arguments filed February 25, 2010 have been fully considered but they are not persuasive.
- 10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the production of very long chain polyunsaturated fatty acids, and a delta-5 elongase limited to C20-C22 fatty acids that does not initiate the several elongation cycles as typical for a mammalian enzyme) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- 11. Applicants assert that Drexler discloses that the delta-5 elongase coding sequence required to practice the invention has not been identified. However, the Examiner maintains that

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Drexler references several prior art elongase genes, including a mammalian elongase and a KCS-cDNA from L. douglasii, for example (see the paragraph bridging pages 795-796), which are considered to be delta-5 elongase coding sequences. The specification does not define what is intended by the term "delta-5 elongase", and it is noted that this term was not used in available online enzyme nomenclature databases. Given the absence of any definition for "delta-5 elongase" that would distinguish it from the prior art elongases taught by Drexler et al, and given the breadth of the claims, which are drawn to the production of fatty acids that are 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds, which would be present at least 1% by weight based on total lipid content in any plant cell regardless of the expression of the nucleic acids that are introduced, the method taught by Drexler et al anticipates the claims.

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 14. Claims 1, 2 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drexler et al (J Plant Physiol 160 (7): 779-802, July 2003 in IDS) taken with Geneseq Accession ABV74260 (Lerchl et al, July 25, 2002).
- 15. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase.

Drexler et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase (see pages 794-796 and Figure 6, for example), wherein genes for each of these enzymes are cloned from eukaryotic organisms and bacteria. Drexler et al also teach transformation of canola (Brassica) with desaturase coding sequences (page 796, the last full paragraph), as stated above.

Drexler et al do not teach the delta-6 desaturase of SEQ ID NO: 23.

Geneseq Accession ABV74260 teaches SEQ ID NO: 23.

Given the teachings of Drexler et al of the desirability of producing very long chain polyunsaturated fatty acids in a plant by transforming a plant with genes encoding a delta-6

elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase, one of ordinary skill in the art would have been motivated to practice the same method and to substitute other known sequences, such as the delta-6 desaturase from Physcomitrella taught by Geneseq Accession ABV74260. And the particular R2 and R3 constituents and levels of polyunsaturated fatty acids would be the optimization of process parameters and would not confer patentable distinction to the claimed invention. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

- 16. Applicants' arguments filed February 25, 2010 have been fully considered but they are not persuasive.
- 17. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the production of very long chain polyunsaturated fatty acids, a delta-5 elongase limited to C20-C22 fatty acids that does not initiate the several elongation cycles as typical for a mammalian enzyme) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- 18. Applicants assert that Drexler discloses that the delta-5 elongase coding sequence required to practice the invention has not been identified. However, the Examiner maintains that Drexler references several prior art elongase genes, including a mammalian elongase and a KCS-cDNA from L. douglasii, for example (see the paragraph bridging pages 795-796), which may be

considered delta-5 elongase coding sequences, and Geneseq Accession ABV74260 does not remedy this deficiency. As stated above, the specification does not define what is intended by the term "delta-5 elongase", and it is noted that this term was not used in available online enzyme nomenclature databases. Given the absence of any definition for "delta-5 elongase" that would distinguish it from the prior art elongases taught by Drexler et al, and given the breadth of the claims, which are drawn to the production of fatty acids that are 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds, the method taught by Drexler et al in combination with Geneseq Accession ABV74260 makes obvious the claims.

- 19. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drexler et al (J Plant Physiol 160 (7): 779-802, July 2003 in IDS) taken with Geneseq Accession ABV74262 (Lerchl et al, March 28, 2003).
- 20. The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase.

Drexler et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase (see pages 794-796 and Figure 6, for example), wherein genes for each

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of these enzymes are cloned from eukaryotic organisms and bacteria. Drexler et al also teach transformation of canola (Brassica) with desaturase coding sequences (page 796, the last full paragraph), including a delta-12 desaturase coding sequence for the production of gamma-linolenic acid (18:3).

Drexler et al do not teach a delta-12 desaturase of SEQ ID NO: 110.

Geneseq Accession ABV74262 teaches a sequence 62.9% identical to SEQ ID NO: 110.

Given the teachings of Drexler et al of the desirability of producing long chain polyunsaturated fatty acids in a plant by transforming a plant with genes encoding a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, a delta-4 desaturase, and a delta-12 desaturase, one of ordinary skill in the art would have been motivated to practice the same method and to substitute other known sequences, such as the delta-12 desaturase from Phaeodactylum taught by Geneseq Accession ABV74262 or any other delta-12 desaturase. And the particular R2 and R3 constituents and levels of polyunsaturated fatty acids would be the optimization of process parameters and would not confer patentable distinction to the claimed invention. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

- 21. Applicants' arguments filed February 25, 2010 have been fully considered but they are not persuasive.
- 22. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the production of very long chain polyunsaturated fatty acids, a delta-5 elongase limited to C20-C22 fatty acids

that does not initiate the several elongation cycles as typical for a mammalian enzyme) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

- 23. Applicants assert that Drexler discloses that the delta-5 elongase coding sequence required to practice the invention has not been identified. However, the Examiner maintains that Drexler references several prior art elongase genes, including a mammalian elongase and a KCS-cDNA from L. douglasii, for example (see the paragraph bridging pages 795-796), which may be considered delta-5 elongase coding sequences, and Geneseq Accession ABV74262 does not remedy this deficiency. As stated above, the specification does not define what is intended by the term "delta-5 elongase", and it is noted that this term was not used in available online enzyme nomenclature databases. Given the absence of any definition for "delta-5 elongase" that would distinguish it from the prior art elongases taught by Drexler et al, and given the breadth of the claims, which are drawn to the production of fatty acids that are 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds, it appears that the method taught by Drexler et al makes obvious the claims in combination with Geneseq Accession ABV74262 that is similar to SEQ ID NO: 110 or in combination with any other delta-12 desaturase coding sequence. It is noted that the claim recites a genus of delta-12 desaturase coding sequences.
- 24. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drexler et al (J Plant Physiol 160 (7): 779-802, July 2003 in IDS) taken with EST Accession BE777235 (Kamoun et al September 20, 2000).

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The claims are drawn to a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, a delta-4 desaturase and an omega-3 desaturase. Drexler et al also teach transformation of canola (Brassica) with additional desaturase coding sequences (page 796, the last full paragraph), such as a delta-12 desaturase coding sequence for the production of polyunsaturated fatty acids.

Drexler et al teach a process to produce compounds of Formula I having from 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds in an organism with at least 1% of these compounds based on total lipid content by introducing into the organism coding sequences for a delta-6 elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, and a delta-4 desaturase (see pages 794-796 and Figure 6, for example), wherein genes for each of these enzymes are cloned from eukaryotic organisms and bacteria. Drexler et al also teach transformation of canola (Brassica) with desaturase coding sequences (page 796, the last full paragraph), including a delta-12 desaturase coding sequence for the production of polyunsaturated fatty acids in a plant.

Drexler et al do not teach an omega-3 desaturase of SEQ ID NO: 88.

EST Accession BE777235 discloses an omega-3 desaturase having 60% sequence identity to SEQ ID NO: 88.

Given the teachings of Drexler et al of the desirability of producing long chain polyunsaturated fatty acids in a plant by transforming a plant with genes encoding a delta-6

elongase, a delta-6 desaturase, a delta-5 desaturase, a delta-5 elongase, a delta-4 desaturase, and a delta-12 desaturase, one of ordinary skill in the art would have been motivated to practice the same method and to substitute other known sequences in the omega-3 pathway, such as the omega-3 desaturase of EST Accession BE777235. And the particular R2 and R3 constituents and levels of polyunsaturated fatty acids would be the optimization of process parameters and would not confer patentable distinction to the claimed invention. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

- 25. Applicants' arguments filed February 25, 2010 have been fully considered but they are not persuasive.
- 26. In response to applicants' argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the production of very long chain polyunsaturated fatty acids, a delta-5 elongase limited to C20-C22 fatty acids that does not initiate the several elongation cycles as typical for a mammalian enzyme) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
- 27. Applicants assert that Drexler discloses that the delta-5 elongase coding sequence required to practice the invention has not been identified. However, the Examiner maintains that Drexler references several prior art elongase genes, including a mammalian elongase and a KCS-cDNA from L. douglasii, for example (see the paragraph bridging pages 795-796), which may be considered delta-5 elongase coding sequences, and Geneseq Accession ABV74260 does not

remedy this deficiency. As stated above, the specification does not define what is intended by the term "delta-5 elongase", and it is noted that this term was not used in available online enzyme nomenclature databases. Given the absence of any definition for "delta-5 elongase" that would distinguish it from the prior art elongases taught by Drexler et al, and given the breadth of the claims, which are drawn to the production of fatty acids that are 9 carbons to 31 carbons and having from 2 double bonds to 6 double bonds, it appears that the method taught by Drexler et al makes obvious the claims in combination with EST Accession BE777235 or any other omega-3 desaturase sequences. It is noted that the claim recites a genus of omega-3 desaturase coding sequences.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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No claims are allowed.

Applicant is advised that of the sequences that were elected, SEQ ID NO: 77 encoding SEQ ID NO: 78 is the only sequence pair that was searched and found to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EFM

/Elizabeth F. McElwain/ Primary Examiner, Art Unit 1638